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## Attorneys for Plaintiff PharmaTech Solutions, Inc.

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA

PHARMATECH SOLUTIONS, INC.

**Plaintiff,**

## SHASTA TECHNOLOGIES, LLC,

**Defendant.**

Case No.: 5:14-cv-03682 BLF

**FIRST AMENDED COMPLAINT FOR  
DECLARATORY AND INJUNCTIVE  
RELIEF RE WRITTEN TERM SHEET**

Plaintiff PharmaTech Solutions, Inc. hereby alleges as its First Amended Complaint for Declaratory and Injunctive relief as follows.

I.

## **JURISDICTION**

1. This Court has jurisdiction pursuant to Title 28, United States Code Section 1332.

II.

## VENUE

2. Venue is proper in this Court because the actions complained of herein occurred in this judicial district, and because the same parties are already before this Court in the following matters: (i) a patent infringement action brought by Lifescan Scotland against Defendants Shasta and PharmaTech, *inter alia*, entitled *Lifescan Scotland Ltd. v. Shasta Technologies, LLC, et. al.*, Case, No. CV11-04494 (U.S.D.C. N.D. Cal. San Jose Div.) (hereafter the “Patent Action”); (ii) a Lanham Act violation brought by Lifescan against Shasta and PharmaTech, *inter alia*, entitled *Lifescan, Inc. v. Shasta Technologies, LLC, et. al.*, Case No, 12 CV-06360 (U.S.D.C N.D. Cal. San Jose Div.) (hereafter the “Lanham Act Action”); and (iii) an interpleader action brought by Shasta’s insurance company against Shasta, and its additional insured PharmaTech, over how the carrier’s remaining policy limits were to be distributed in defending the Patent Action, entitled *Gotham Insurance Company v. Shasta Technologies, LLC, et. al.*, Case No. CV13-03810 (U.S.D.C. N.D. Cal San Jose Div.) (Hereafter the “Interpleader Action.”)

III.

## **FACTS COMMON TO ALL CAUSES OF ACTION**

### a. The Parties

3. Plaintiff PharmaTech Solutions, Inc. (hereafter "PharmaTech") is a Nevada Corporation. with its principal executive offices located at 925 Borom Road, York, Pennsylvania. (*Infra.*)

4. Defendant Shasta Technologies, LLC (hereafter “Shasta”), is an Oregon limited liability company, with its principal place of business at 16923 SW Richen Park Circle, Sherwood, Oregon.

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1                   b.     **The GenStrip Product**

2       5.     In 2011, Shasta was the owner of a product known as the GenStrip. The  
3     GenStrip is a diagnostic test strip to be used in conjunction with diagnostic test meters,  
4     i.e., devices that measure a person's blood sugar at any particular point in time. The  
5     GenStrip is manufactured for Shasta by a company called Conductive Technologies,  
6     Inc. (hereafter "CTI.")

7

8                   c.     **The Exclusive Distributorship Agreement**

9       6.     On or about June 20, 2011, PharmaTech entered into an Exclusive  
10   Distributorship Agreement with Shasta, and Broadtree Inc. (hereafter "Broadtree"), an  
11   investor in Shasta, to distribute the GenStrip.

12

13                   d.     **The Lanham Act Action**

14       7.     Under the Distributorship Agreement, PharmaTech ordered and paid for  
15   approximately 95,000 GenStrip boxes from CTI in February and March 2013 of which  
16   approximately 25,000 were delivered. Another 60,000 GenStrip boxes were  
17   manufactured but not delivered. A problem then developed as Shasta had placed on  
18   these boxes the logo of Johnson & Johnson, and its subsidiary, Lifescan (hereafter  
19   collectively referred to as "Lifescan"), along with a photograph of Lifescan's "One  
20   Touch" blood monitoring device, without Lifescan's prior knowledge, authorization or  
21   consent. Consequently, Lifescan sued Shasta, PharmaTech, and CTI in federal court for,  
22   *inter alia*, violations of the Lanham Act. (*Supra*.)

23       8.     On May 21, 2013, the United States District Court, Northern District of  
24   California, issued a Preliminary Injunction against the Defendants precluding them from  
25   using any GenStrip boxes in the future so long as the Lifescan logo and One Touch  
26   photograph remained thereon. This Preliminary Injunction was modified slightly by the  
27   Court on June 24, 2013 to permit Defendants to use a photograph of the "One Touch"  
28

1 on the inside materials of the box only to demonstrate that the GenStrip was compatible  
2 with the One Touch device.

3       9.     In view of the foregoing, it was necessary for PharmaTech to order  
4 replacement boxes in new packaging and to pay the labor necessary to assemble the new  
5 packages in order to comply with the Court's Preliminary Injunction. Accordingly,  
6 PharmaTech ordered 74,256 replacement GenStrip boxes from CTI between October 23  
7 and December 2, 2013. Emails from Mr. Knickerbocker, Sr., the Managing Member of  
8 Shasta, and a resident in the Northern District of California, confirmed that PharmaTech  
9 had paid for these boxes and, as such, Mr. Knickerbocker, Sr., on behalf of Shasta,  
10 authorized their delivery to PharmaTech.

11

12       f.     The FDA's Inspection of Shasta's Alleged Manufacturing Facility

13       10.    During December 2013, the United States Food and Drug Administration  
14 (hereafter "FDA") conducted a surprise inspection of Shasta's alleged manufacturing  
15 facility at 16923 SW Richen Park Circle, Sherwood, Oregon. Upon inspection, Shasta's  
16 alleged facility was determined to be only the residential home of one of Shasta's  
17 owners and members, Calvin A. Knickerbocker III. The FDA determined that this  
18 residence was not a manufacturing facility, nor could any type of quality control and/or  
19 compliance with the FDA's regulation take place at this house.

20       11.    Accordingly, Shasta, through the representations of both Calvin A.  
21 Knickerbocker III, and his father, Calvin A. Knickerbocker, Jr., the Managing Member  
22 of Shasta, represented to the FDA that the manufacturers of the GenStrip were CTI and  
23 PharmaTech. This representation to the FDA as to PharmaTech was without  
24 PharmaTech's knowledge, authorization, or consent.

25       12.    Upon discovery of the above facts, PharmaTech's Board of Directors,  
26 consisting of Keith Berman, and Robert Jagunich, located in California, and William  
27 Lyons, located in Naperville, Illinois, held a telephonic Board of Directors meeting on  
28 March 5, 2014 (prior to the filing of this action) in an attempt to prevent the FDA from

1 issuing a directive removing the GenStrip from the market, and to keep the GenStrip  
2 product “alive.” At this meeting, PharmaTech’s Board of Directors resolved to: (i)  
3 execute a binding term sheet to purchase the GenStrip and its Mark from Shasta; (ii) to  
4 hire a consultant, authorized by CTI, to write and implement a suitable quality plan  
5 meeting all FDA standards and applicable regulations with respect to the GenStrip to be  
6 jointly administered by PharmaTech and CTI; (iii) to change the principal executive  
7 offices of PharmaTech to 925 Borom Road, York Pennsylvania; and to register  
8 PharmaTech as a foreign corporation authorized to duly conduct business in  
9 Pennsylvania.

10 13. PharmaTech has taken each of the above steps, including entering into a  
11 Quality Control Agreement with CTI on or about April 21, 2014. The FDA has also  
12 registered PharmaTech’s 935 Borom Road York, Pennsylvania address (PharmaTech  
13 has since moved next door from its prior 925 Borom Road address) as the official  
14 facility registration for PharmaTech, and PharmaTech has been certified as a by the  
15 Pennsylvania Secretary of State as a foreign corporation duly authorized to conduct  
16 business in Pennsylvania.

17 14. Furthermore, as the GenStrip is manufactured in York, Pennsylvania,  
18 PharmaTech’s President, Secretary and Treasurer, Keith Berman, travels to York,  
19 Pennsylvania on a bi-weekly basis to meet with CTI to insure that compliance with its  
20 Quality Control Agreement with CTI, and all applicable FDA regulations, are  
21 continuing, and to make, then and there, any decisions with respect to the same, and any  
22 future developmental plans for the GenStrip, including, but not limited to, quality  
23 control issues, audit procedure controls, Medical Device Reporting issues (“MDR”  
24 reviews), CTI management reviews, design control issues, document management and  
25 control issues, purchasing controls, and to review the format, layout, abbreviation for  
26 expiration date and lot number for the distribution of the GenStrip, and to determine the  
27 useful shelf life of the GenStrip. Consequently, PharmaTech’s “nerve center” with  
28 respect to the GenStrip, is in York, Pennsylvania.

## **The FDA's Warning Letters**

15. In the interim, on April 8, 2014, Shasta received a harsh warning letter from the United States Food and Drug Administration (hereafter "FDA") because of the Shasta's improprieties found by the FDA during its December 2013 inspection. (See Exhibit A, attached hereto, which is a true and accurate copy of this letter.) The FDA demanded that Shasta take remedial action promptly, and memorialized this demand in an April 8, 2014 Warning Letter. This Warning Letter also contained an FDA demand for a voluntary recall of GenStrip. Shasta did not respond to the FDA's April 8, 2014 letter.

16. Shasta's noncompliance prompted the FDA to issue a subsequently Worldwide Safety Warning Letter on April 29, 2014 to users, distributors, physicians, and other parties interested in the GenStrip, halting the sale, use, and advertisement of the GenStrip. The FDA also warned diabetics against using the GenStrip in the future, and even took the unprecedented action of requesting that users, sellers, distributors, *return* any purchases of the GenStrip to the original point of sale. (See Exhibit B, attached hereto, which is a true and accurate copy of this Safety Warning Letter.) In the drug industry, this FDA action is known as the "death penalty."

17. Because the 74,256 GenStrip boxes PharmaTech had ordered from CTI have Shasta's name and logo thereon (in place of the Lifescan logo), and because Shasta can no longer market the GenStrip in view of the FDA's April 29, 2014 Safety Warning Letter, PharmaTech has calculated that it will be forced over the next two years (the length of time FDA requires for product actions of this nature) to "take back" and replace, as unsafe, approximately 50,040 GenStrip boxes out of its original 74,256 CTI order. Accordingly, PharmaTech has ordered 50,040 replacement boxes from CTI.

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27 //  
28 //

**FIRST CAUSE OF ACTION FOR**  
**DECLARATORY AND INJUNCTIVE RELIEF**  
**RE THE PARTIES BINDING WRITTEN TERM SHEET**

18. Plaintiff re-alleges and incorporates by reference herein paragraphs 1 through 17, above, as if fully set forth herein.

19. Notwithstanding the Lanham Action, on March 20, 2014, PharmaTech, Shasta, and Broadtree entered into a written binding Term Sheet under which PharmaTech agreed to purchase the GenStrip from Shasta. (Exhibit C, attached hereto, is a true and accurate copy of this Term Sheet.)<sup>1</sup>

20. Although the purchase price for the GenStrip was initially set at \$2 million, PharmaTech agreed to this price before learning that Shasta had disingenuously minimized and concealed the seriousness of Shasta's problems with the FDA. Indeed, the FDA's April 8 and 29, 2014 letters, which now effectively preclude PharmaTech from using, selling, or marketing the GenStrip so long as Shasta is associated with it, were not issued, or provided to PharmaTech until many weeks after the Term Sheet was signed. Nevertheless, PharmaTech is informed and believes, and on this basis alleges, that Shasta knew its problems with the FDA were much more serious than simply removing the Lifescan logo and photographs of the Lifescan One Touch Machine from its packaging. In short, the full extent of Shasta's problems with the FDA has caused PharmaTech great, and irreparable damage with its customers and in the medical marketplace in which PharmaTech operates, the exact nature of which may be difficult, if not impossible, to calculate.

21. For example, to correct Shasta's misappropriation of Lifescan's One touch photograph, quality deficiencies, errors, issues with the FDA, and to be able to sell the product that it has already purchased, PharmaTech has incurred damages of (i) \$157,992.84

<sup>1</sup> Broadtree's only involvement in this Term Sheet is its agreement to accept \$388,923.00 from Shasta under Shasta's Operating Agreement in repayment of its investment. This issue does not involve the purchase price controversy between PharmaTech and Shasta, as Broadtree receives the same amount regardless of any purchase price adjustment to Shasta. (*Infra.*)

1 in buying the first batch of replacement boxes, i.e., \$109,992.84 to Shasta, and \$48,000  
 2 to CTI (see Exhibits D and E, attached hereto); (ii) \$318,682.00 from CTI alone for the  
 3 50,040 GenStrip boxes that it has already ordered as the second batch of replacements  
 4 (see Exhibit F, attached hereto); (iii) approximately the amount in of approximately  
 5 \$76,829.17 that CTI has informed PharmaTech it will have to pay for packing materials  
 6 that can no longer be used in view of the GenStrip repackaging (see Exhibit G, attached  
 7 hereto); and (iv) a future amount to replace 24,216 remaining GenStrip boxes (out of the  
 8 first replacement batch of 74,256) that have yet to be returned.<sup>2</sup>

9       22. Finally, Shasta has falsely represented to the FDA that PharmaTech is the  
 10 “manufacturer” (as that term is defined by the FDA) of the GenStrip in a disingenuous  
 11 attempt to avoid the effects of the FDA’s April 8, Warning Letter it had previously  
 12 received pertaining to Shasta’s failures to comply with all federal regulations in acting as  
 13 the GenStrip manufacturer. As a direct and proximate result of Shasta’s  
 14 misrepresentation and interference with PharmaTech’s business, the FDA issued a  
 15 Warning Letter to PharmaTech on or about July 7, 2014, which requires PharmaTech to  
 16 now incur fees and costs in defending itself against Shasta’s initial false characterization  
 17 in December 2013 that PharmaTech was the GenStrip manufacturer.<sup>3</sup>

18       23. In addition, Shasta has continued to intentionally interfere with  
 19 PharmaTech’s attempts to distribute and market the GenStrip, by, among other things,  
 20 continuing to make false statements to the FDA, and to PharmaTech’s FDA counsel,  
 21 Mark Duval, about PharmaTech and its counsel’s representation of PharmaTech before  
 22 the FDA.

23  
 24  
 25 <sup>2</sup> PharmaTech’s cost for the second batch of 50,040 replacement boxes was greater than its  
 26 purchase of the first batch of 74,256 replacement boxes because PharmaTech’s royalty rate to  
 Shasta had increased by this time.

27 <sup>3</sup> Shasta also made the same misrepresentations to the FDA concerning CTI, i.e., that CTI was  
 28 the “manufacturer” of the GenStrip, which resulted in the FDA recently sending CTI its own  
 Warning Letter.

1       24. The end result of all of Shasta's misconduct, as described herein, is the  
2 damage that PharmaTech has suffered, and will continue to suffer, to its reputation in the  
3 marketplace, from being associated with a "tainted" product deemed "unsafe" by the  
4 FDA, including, but not limited to, the loss of income from various entities that are no  
5 longer willing to do business with PharmaTech.

6       25. Under the circumstances, there is a present controversy in that Shasta is  
7 demanding payment of the full \$2 million purchase price, notwithstanding the totality of  
8 the damages Shasta has caused PharmaTech. Conversely, PharmaTech, which is still  
9 willing to purchase the GenStrip product from Shasta, but contends that the \$2 million  
10 purchase price must be reduced and offset by the damages PharmaTech has incurred, and  
11 will continue to incur.

12       26. Consequently, PharmaTech seeks a declaration from this Court that it is  
13 entitled to offset the \$2 million dollar purchase price with evidence of the damages  
14 PharmaTech has incurred, and will continue to incur.

15       27. Furthermore, under paragraph 19 of the Term Sheet, Shasta is obligated to  
16 immediately transfer to PharmaTech the Manufacturing Agreement for the GenStrip that  
17 it has with CTI, which was previously assigned to PharmaTech with both CTI's and  
18 Shasta's consent. The purpose of this assignment, and the transfer provision in the Term  
19 Sheet, was to prevent Shasta from interfering with any orders for GenStrip products  
20 and/or boxes that PharmaTech might order from CTI. To date, despite many demands,  
21 Shasta has failed and refused to transfer the GenStrip Manufacturing Agreement to  
22 PharmaTech.

23       28. Accordingly, PharmaTech seeks an injunction from this Court that Shasta  
24 immediately transfer the Manufacturing Agreement to PharmaTech, and that Shasta be  
25 restrained and enjoined from interfering with the delivery of GenStrip products ordered  
26 by PharmaTech from CTI.

27  
28       WHEREFORE, PharmaTech prays as follows:

1. For a declaration from this Court that PharmaTech is entitled to offset the
2. \$2 million dollar Term Sheet purchase price with evidence of the damages
3. PharmaTech has incurred, and will continue to incur, from Shasta's
4. acts/and failures to act;
5. For an injunction from this Court that Shasta immediately transfer the
6. Manufacturing Agreement to PharmaTech, and that Shasta be restrained
7. and enjoined from interfering with the delivery of GenStrip products
8. ordered by PharmaTech from CTI;
9. For costs of suit incurred herein;
10. For reasonable attorneys' fees incurred on its First Cause of Action; and
11. For such other and further relief as this Court deems just and proper.

12  
13 DATED: 2/20, 2015

14 BAER & TROFF LLP

15 By: 

16 ERIC TROFF,  
17 Attorneys for Plaintiff  
18 PharmaTech Solutions, Inc.

**EXHIBIT A**

Home Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters 2014

**Inspections, Compliance, Enforcement, and Criminal Investigations**

**Shasta Technologies, LLC 4/8/14**



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Seattle District  
Pacific Region  
22215 26<sup>th</sup> Ave SE, Suite 210  
Bothell, WA 98021  
Telephone: 425-302-0340  
FAX: 425-302-0402

April 8, 2014

**OVERNIGHT DELIVERY  
SIGNATURE REQUIRED**

In reply refer to Warning Letter SEA 14-08

Calvin A. Knickerbocker II  
President and Managing Member  
Shasta Technologies, LLC  
3257 Highway 128  
Calistoga, California 94515

**WARNING LETTER**

Dear Mr. Knickerbocker:

During an inspection of your firm located at 16923 SW Richen Park Circle, Sherwood, Oregon, on December 2, 2013 through December 9, 2013, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures the GenStrip Blood Glucose Test Strips. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

This inspection revealed that this device is adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System Regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received a response from you dated December 30, 2013, concerning our investigators' observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, that was issued to Mr. Calvin Knickerbocker III, your firm's general counsel (responsible for regulatory operations and quality systems), on December 9, 2013. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 2 CFR 820.100(a). Specifically, no corrective and preventive action procedures were available for review upon request by the investigator. Mr. Calvin Knickerbocker III indicated that Shasta does not have CAPA procedures.

Your firm's response is not adequate. Your firm provided the Quality Manual Doc No. QS-1001, which states that Quality Manual Doc No. QS-1001 section 14.0 Corrective and Preventive Action describes the Shasta Technologies CAPA activities and that it relies on its contractor's CAPA procedures because all manufacturing and distribution is performed by the contract manufacturers. However, this is not adequate because this does not specify your firm's involvement or responsibility for the corrective and preventive action procedure. Your firm did not provide evidence of a procedure that describes analyzing the corrective and preventive action processes, investigating the cause of nonconformities relating to the product, verifying or validating the corrective and preventive action, implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems, ensuring that information related to quality problems is disseminated to those directly responsible for assuring the quality of the product, and submitting relevant information on identified quality problems.

*-EX, A -*

and corrective and preventive actions for management review as required by the CAPA requirements of 21 CFR 820.100. You firm did not provide evidence of a retrospective review of other procedures pertaining to the CAPA subsystem, such as complaint handling and nonconformance procedures, to ensure they were documented as required.

2. Failure to maintain complaint files and to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Specifically, no complaint handling procedures were available for review upon request by the investigator. Mr. Calvin Knickerbocker III indicated that Shasta does not have complaint handling procedures although he reviews consumer reviews on the Internet and thus is conducting complaint handling activities for Shasta.

Your firm's response is not adequate. You have stated that procedures for receiving, reviewing and evaluating complaints are maintained by your contract manufacturers. Your firm did not provide evidence of a procedure that describes how complaints are processed in a uniform and timely manner, how oral complaints are documented, how complaints are evaluated to determine whether the complaint should be reported to FDA under part 803, and how complaints are reviewed and evaluated to determine whether an investigation is necessary as required by 21 CFR 820.198(a). In addition, your firm has not provided evidence that the consumer reviews Mr. Calvin Knickerbocker III reviewed on the Internet and any other complaints were documented as required by your firm's complaint handling procedure.

3. Failure to establish and maintain procedures to control the design of the device to ensure that specified design requirements are met, as required by 21 CFR 820.30(a). Specifically, no design control procedures were available for review upon request by the investigator. The Genstrip Master Quality Plan, Revision A, release date September 19, 2013, indicates that Shasta is responsible for design controls for the GenStrip Blood Glucose Test Strips including "setting the product requirements". Mr. Calvin Knickerbocker III indicated that Shasta does not maintain design records covering GenStrip Blood Glucose Test Strips.

Your firm's response is not adequate. Your firm has not provided design control procedures in its response. Additionally, your firm has not indicated that a retrospective review was completed of the GenStrip Blood Glucose Test Strips to ensure design controls were completed as required.

4. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example, no purchasing control procedures were available for review upon request by the investigator. Shasta contracts out manufacturing, marketing, and complaint handling for GenStrip Blood Glucose Test Strips. Specifically, your firm has indicated that contractors (b)(4) are responsible for document controls, purchasing controls, and CAPA, and that (b)(4) is responsible for handling complaints. However, your firm did not provide evidence that it has defined, documented, and implemented purchasing control procedures to describe how it controls services provided by these contractors. Mr. Calvin Knickerbocker III indicated that Shasta does not have purchasing control procedures.

Your firm's response is not adequate. Your firm provided a Quality Manual, dated effective as of December 31, 2013, which states that Shasta Technologies, LLC has established purchasing procedures; however, your firm has not provided evidence that it has implemented and maintained the purchasing controls procedure. Your firm did not provide evidence to demonstrate that purchasing control procedures ensured that all purchased or received product and services from the designated contractors met specified requirements. Additionally, your firm did not provide evidence of training on the new purchasing controls procedures and did not provide a copy of this procedure.

5. Failure to establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants, as required by 21 CFR 820.50(a). For example, your firm does not maintain documented evaluation of suppliers and contractors it uses to conduct manufacturing, marketing, and complaint handling for GenStrip Blood Glucose Test Strips. Your firm does not maintain documented evaluation of activities that the contract manufacturer conducts, including process validation, nonconforming product, acceptance activities, labeling and packaging in the manufacture of GenStrip Blood Glucose Test Strips. Mr. Calvin Knickerbocker III indicated that he would decline to provide the investigator documentation of contractor evaluation.

Your firm's response is not adequate. You have stated that you are in the process of addressing the continued qualification of the contract manufacturers by participation in routine management review meetings and yearly internal audits that will be completed by February 28, 2014. However, you have not provided evidence of performing previous management reviews and internal audits of the suppliers and have not provided any evidence that you have established procedures to evaluate and select potential suppliers, contractors and consultants for the GenStrip Blood Glucose Test Strips as required by 21 CFR 820.50(a). In addition, your firm did not provide evidence that specified the level of control over the contractors and the designated responsibilities, nor did your firm provide evidence that it has conducted a retrospective review of all suppliers to ensure that they were evaluated and selected as required.

6. Failure to establish and maintain procedures to control all documents, as required by 21 CFR 820.40. Specifically, no document control procedures were available for review upon request by the investigator. Mr. Calvin Knickerbocker III indicated that Shasta does not have document control procedures. According to the Genstrip Master Quality Plan, Revision A, release date September 19, 2013, and signed by Mr. Knickerbocker, Shasta is responsible for document controls.

Your firm's response is not adequate. Your firm has stated that it relies on its contract manufacturers for document control. However, this is not adequate because your firm did not provide evidence that it has established and maintained document control procedures as required by 21 CFR 820.40. Your firm did not provide evidence of a procedure that

designates an individual to approve and distribute documents, or to review and approve changes to the documents. Additionally, your firm did not indicate that a retrospective review of all documents to ensure that they were controlled as required was performed.

7. Failure to establish policy and objectives for, and commitment to, quality by the management with executive responsibility, as required by 21 CFR 820.20(a). Specifically, no quality policy was available for review upon request by the Investigator. Mr. Calvin Knickerbocker III indicated that Shasta does not have a quality policy. According to the Genstrip Master Quality Plan, Revision A, release date September 19, 2013, Shasta has responsibility for Management Responsibility including a Quality Policy.

Your firm's response is not adequate. Your firm has stated that a quality system policy exists and has been established with executive responsibility at the contract manufacturers. Additionally, your firm states that the Quality Manual Doc No. QS-100: Section 1.0 Management Responsibility defines your firm's management responsibility, quality policy, organizations, and responsibility and authority. However, your firm did not indicate that it conducted a retrospective review of the quality management system to ensure that all procedures were established as required and did not provide a copy of the quality policy and evidence that employees were trained on the policy.

8. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c). Specifically, no procedures for management review were available for review upon request by the Investigator. Mr. Calvin Knickerbocker III indicated that Shasta does not have management review procedures.

Your firm's response is not adequate. Your firm has stated procedures for management review exist at the contract manufacturers and that your firm plans to participate in the contract manufacturer's routine review of the quality procedures for the GenStrip Blood Glucose Test Strips manufacturing and distribution and that your firm plans to complete this by February 28, 2014, and it would ensure that these reviews were conducted as required. However, this response is inadequate because your firm did not provide evidence that it established procedures to review the suitability and effectiveness of its quality system at defined intervals. In addition, your firm did not provide evidence that the management reviews were completed as required and that employees would be trained on the new procedures.

9. Failure to establish quality system procedures and instructions, as required by 21 CFR 820.20(e). Specifically, no quality system procedures and instructions were available for review upon request by the Investigator. Mr. Calvin Knickerbocker III indicated that Shasta does not have quality system procedures. According to the Genstrip Master Quality Plan, Revision A, release date September 19, 2013, and signed by Mr. Knickerbocker, "Each company will maintain a quality system that is consistent with its project role."

Your firm's response is not adequate. Your firm provided a Quality Manual, dated effective as of December 31, 2013, that includes the title, scope of, applications, definitions, quality policy and objectives, and responsibilities for their quality system procedures; however, this manual was not signed by management. Additionally, your firm provided a Genstrip Master Quality Plan, Revision A, dated September 19, 2013; however, review of the Genstrip Master Quality Plan, Revision A does not specify how your firm has established and maintained quality system procedures and instructions, or how it has established controls over the procedures and instructions developed by contractors as required by 21 CFR 820.20(e). Additionally, your firm did not provide evidence that employees were trained on the provided procedure dated effective as of December 31, 2013.

10. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example:

- No procedures for quality audits were available for review upon request by the Investigator. Mr. Calvin Knickerbocker II indicated that Shasta does not have a quality audit procedure.
- Quality audits have not been performed as indicated by Mr. Calvin Knickerbocker III.

Your firm's response is not adequate. Your firm has stated that the Quality Manual Doc No. QS-1001 Section 4.0 Design Control was prepared to comply with the QS regulation requirements and that it relies on the design control procedures of the contract manufacturers. However, your firm has not provided evidence that it has established and maintained procedures to conduct quality audits to assure that the quality system is in compliance with established quality system requirements and to determine the effectiveness of the quality system. Additionally, your firm has not provided evidence that quality audits have been conducted by your firm as required. In addition, your firm did not provide evidence that a retrospective review of the quality system was conducted to ensure that all procedures were established as required by 21 CFR 820.

11. Failure to maintain a device master record (DMR), as required by 21 CFR 820.181. Specifically, no DMR was available for review upon request by the Investigator. Mr. Calvin Knickerbocker III indicated that Shasta does not maintain a DMR for GenStrip Blood Glucose Test Strips and that he declines to provide the investigator with the DMR during this inspection.

Your firm's response is not adequate. Your firm has stated that it relies on its contract manufacturers for the device master record. However, this is not adequate because your firm is responsible for maintaining this information in a manner that is available for review. Additionally, your firm did not provide a copy of the DMR for the GenStrip Blood Glucose Test Strips and evidence that it completed a retrospective review to ensure that DMRs were maintained as required by 21 CFR 820.181.

This inspection also revealed that your GenStrip Blood Glucose Test Strips labeled for use with Lifescan One Touch Ultra, Ultra2, and UltraMini blood glucose meters "purchased before July 2013" are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) is deemed satisfied when a PMA is pending before the agency. [21 CFR 807.81(b)] The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm><sup>1</sup>. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Additionally, the inspection revealed that your firm's GenStrip Blood Glucose Test Strips are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360l, and 21 CFR Part 803 - Medical Device Reporting. Significant violations include, but are not limited to, the following:

Failure to develop, maintain, and implement written Medical Device Reporting (MDR) procedures, as required by 21 CFR 803.17. For example, written MDR procedures were not available for review upon request by the investigator.

Your firm's response is not adequate. Your firm has stated that MDR procedures have been developed, maintained and implemented by the contract manufacturers. Additionally, you have stated that the Quality Manual Doc No. QS-1001 Section 14.0 Corrective and Preventative Action describes your complaint and MDR handling. However, your firm did not provide evidence that it has developed, maintained, or implemented a written MDR procedure, nor did your firm indicate that it performed a retrospective review of adverse events to ensure that they were reported as required.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to: Patricia A. Pinkerton, Compliance Officer, U.S. Food and Drug Administration, Seattle District Office, 22215 26<sup>th</sup> Ave SE, Suite 210, Bothell, Washington 98021. Refer to WL SEA 14-08 when replying. If you have any questions about the contents of this letter, please contact: Patricia A. Pinkerton, Compliance Officer at 425-302-0428.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,  
 /S/  
 Ann M. Adams, PhD  
 Acting District Director

cc: Mr. Calvin A. Knickerbocker III  
 Shasta Technologies, LLC  
 16923 SW Richen Park Circle  
 Sherwood, Oregon 97140-8682

cc: Dr. Yeung Yu  
 Shasta Technologies, LLC  
 5731 DImas Court

**EXHIBIT B**

**U.S. Food and Drug Administration**  
Protecting and Promoting Your Health

# **Shasta Technologies GenStrip Blood Glucose Test Strips May Report False Results: FDA Safety Communication**

**Date Issued:** April 29, 2014

**Audience:**

- People with type I and type II diabetes who monitor their blood sugar (blood glucose) levels
- Health Care Professionals including pharmacists, clinicians and health educators who provide diabetes care and management
- Pharmacy retailers and wholesalers
- Hospital Supply Managers

**Medical Specialties:** Diabetes Care and Management, Pharmacy

**Product:**

GenStrip Blood Glucose Test Strips, sold by Shasta Technologies LLC, are "third-party" blood glucose monitoring test strips—this means that the test strips are not made by the same company as the meter with which they are used. The strips are used in the home and in health care facilities to measure blood glucose levels in diabetes care and management. Shasta's GenStrips are advertised for use with the LifeScan OneTouch family of glucose meters (e.g. Ultra, Ultra 2 and Ultra Mini).

The affected test strips have been manufactured and distributed since March 2013 and are available through online retailers and retail pharmacies.

**Purpose:**

The FDA is advising people with diabetes and health care professionals to stop using GenStrip Blood Glucose Test Strips because the strips may report incorrect blood glucose levels. The FDA recommends the use of alternative glucose test strips that are designed for use with the LifeScan OneTouch family of glucose meters.

**Summary of Problem and Scope:**

During a recent inspection of Shasta Technologies LLC, the FDA found extensive violations of federal regulations intended to assure the quality of products in the manufacturing of GenStrip Test Strips. These regulations, called quality systems regulations, require manufacturers to establish and document procedures that assure quality, including ways to deal with customer complaints, adverse event reports, and purchasing from suppliers. These regulations also require manufacturers to establish and document procedures for assuring the quality of manufactured product, and for investigating and correcting manufacturing problems.

At an inspection earlier this year, and documented in an April 2014 warning letter, the FDA found that Shasta Technologies did not have in place many of the requirements of a quality system. Without assurance of an adequate quality system, the FDA believes that the strips could report incorrect blood glucose levels.

People with diabetes carefully monitor their blood glucose levels and require urgent treatment for low blood sugar (hypoglycemia) or high blood sugar (hyperglycemia). An inaccurate blood glucose reading could lead to inappropriate or delayed treatment that could significantly harm a patient.

To date, the company has been unwilling to voluntarily recall their test strips, resulting in their continued availability. The FDA recommends that use of Shasta Technologies, LLC GenStrip Test Strips be discontinued.

The FDA has cleared other glucose test strips that are designed for use with the LifeScan OneTouch family of glucose meters. The FDA urges customers to use these alternatives with their LifeScan OneTouch glucose meters.

**Recommendations:**

Identify whether you are using GenStrips glucose test strips. The strips may be packaged in green and white packaging with the GenStrip name on top, similar to those shown below.



**For People with Diabetes:**

- Discontinue use of GenStrip Blood Glucose Test Strips.
- Obtain alternative glucose test strips that are designed for use with the LifeScan OneTouch family of glucose meters.
- Ask your pharmacist or contact your diabetes care provider if you need help determining which test strips to use with your glucose meter.
- As always, be aware of symptoms of high blood sugar (hyperglycemia) and low blood sugar (hypoglycemia). If you experience symptoms of either high or low blood sugar, contact your diabetes care provider for advice on treatment.

**For Health Care Providers:**

- Discontinue use of GenStrip Blood Glucose Test Strips.
- Obtain alternative glucose test strips that are designed for use with the LifeScan OneTouch family of glucose meters.

**For Distributors/Retailers:**

- Discontinue sale and distribution of GenStrip Glucose Test Strips.
- Remove unsold product from shelves.

**FDA Activities:**

On April 8, 2014, the FDA sent a [Warning Letter](#) ([/ICECI/EnforcementActions/WarningLetters/2014/ucm392903.htm](#)) to Shasta Technologies LLC for violations of Federal Quality Systems Regulations.

**Reporting Problems to the FDA:**

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

If you suspect or experience a problem with GenStrip Blood Glucose Test Strips, we encourage you to file a voluntary report through [MedWatch, the FDA Safety Information and Adverse Event Reporting program \(/Safety/MedWatch/HowToReport/default.htm\)](#). Health care personnel employed by facilities that are subject to [FDA's user facility reporting requirements \(/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm\)](#) should follow the reporting procedures established by their facilities.

**Other Resources:**

- [FDA Diabetes Information for Consumers \(/ForConsumers/ByAudience/ForPatientAdvocates/DiabetesInfo/default.htm\)](#)
- [Warning Letter to Shasta Technologies LLC \(/ICECI/EnforcementActions/WarningLetters/2014/ucm392903.htm\)](#)

**Contact Information:**

If you have questions about this communication, please contact the Division of Industry Communication and Education (DICE) at [DICE@FDA.HHS.GOV](mailto:DICE@FDA.HHS.GOV) (<mailto:DICE@FDA.HHS.GOV>), 800-638-2041, or 301-796-7100.

**EXHIBIT C**

**Binding Term Sheet for the GenStrip Technology Buyout from Shasta by PharmaTech**

The following has been electronically sent on March 18, 2014 to the following parties for signature:

Calvin Knickerbocker, Sr., Managing Member of Shasta Technologies, LLC

Keith Berman, President of PharmaTech Solutions, Inc.

Rita Chasco, President of Broadtree, Inc.

By signing this binding Term Sheet, each signer agrees to abide by these terms herein as an individual, and as the representative of their respective companies, and that they have the full authority to sign on behalf of their respective entities. Each signer further agrees to fully cooperate in the preparation and signing of this Term Sheet and the final settlement agreement to follow.

The following are the Buyout terms as agreed to by the parties above:

1. The Buyout is for Shasta's intellectual property (technology, marks, goodwill and 510(k), etc. and whatever is usual and customary for asset acquisitions of this nature), but not for the acquisition of Shasta as an entity. A further description of this intellectual property will be provided prior to the completion of a subsequent long form written Settlement Agreement (hereafter "Settlement Agreement"), and agreed to by the parties hereto.
2. The Buyout amount of \$2,000,000.00 will be placed into escrow within 15 days of the signing of the Settlement Agreement.
3. Subject to Section 4, the initial payment to Shasta will be a non-refundable \$50,000 with 7.5% (\$3,750) to be paid directly to Broadtree.
4. Schedule: Shasta will have: (i) 5 business days to reach a written understanding with Ropers Majeski (hereafter "Ropers") regarding the settlement amount of their fees. A copy of the understanding with Ropers will be sent to escrow which will trigger a transfer of the \$50,000 described in paragraph 3 above; (ii) 15 days to execute the Settlement Agreement; (iii) 60 days to determine whether the "483" issues have been settled, and to release the \$2,000,000 (the 60-day period can be extended with written permission of all parties); and (iv) the time to start formal documentation begins on the date this Term Sheet is signed by Shasta, Broadtree and PharmaTech.
5. The definition of when the "483" matter is settled for release of \$2,000,000 must be an objective set of circumstances which a third-party escrow agent can act upon. The wording of this objective is to follow and will be included in the Settlement Agreement.
6. Shasta will execute all documents and place them in escrow as needed to withdraw from all appropriate FDA data bases relative to GenStrip, and Shasta will assist PharmaTech in replacing Shasta in these FDA databases upon the signing of the Term Sheet. Escrow holder to release documents to PharmaTech simultaneously with release of all escrowed funds (\$2,000,000 + \$478,000 to Shasta). The final description of these actions will be described in the Settlement Agreement.
7. Shasta, through its managing member, will sign a release form that PharmaTech and CTI may use in responding to their respective Form 483 letters from FDA, which will state to the FDA and the public (through announcement and/or Form 8K filing), stating that Shasta and its members no longer have any involvement in GenStrip, either as a working partner, or as previous owner of the design. The release forms will be held in escrow and released to PharmaTech simultaneously with the release of all escrowed funds (\$2,000,000 + \$478,000 to Shasta.)

8. Shasta, Broadtree and PharmaTech will sign a dissolution of the June 2011 Distribution Agreement concurrently with the closing of Escrow and distribution of funds (\$2,000,000).
9. The Insurance proceeds paid to Shasta/Ropers from IPISC/Gotham insurance fund, i.e., \$478,000.00, will be placed into escrow. Shasta will grant Lathrup a Power of Attorney to defend all named parties against all claims in the trademark and patent suits. (Hereafter the "Litigation.") Pursuant to the Power of Attorney, Shasta is agreeing that its role in the Litigation has ended. Lathrup shall agree to defend Shasta in the Litigation (as consideration for the \$50,000 fee paid). Shasta to secure Ropers' substitution of counsel documents immediately upon the execution of this Term Sheet. Ropers to agree to full fee payment "walk-away" before the execution of this Term Sheet and the Settlement Agreement to follow, within 48 hours of receipt of the Term Sheet. It is expected that Shasta will come to verbal agreement with Ropers within the next 72 hours.
10. Ropers will withdraw as counsel of record in the Litigation concurrently with the execution of the Power of Attorney granted to Lathrup by Shasta. Further PharmaTech shall not be responsible now or into the future for any monies owed to Ropers, or to Shasta's counsel Randy Hess ("Hess").
11. Shasta is responsible for satisfying its all payables to Ropers, and to Hess, not covered by the \$478K from the insurer, and Ropers will sign a release of all claims against PharmaTech, including that Shasta will have no further liabilities, or expenses arising out of the Litigation upon the execution of the Settlement Agreement. The parties' attorneys will craft language to memorialize this in the Settlement Agreement.
12. PharmaTech will take full responsibility for all payables due Attorney Duval except for those amounts due Attorney DuVal due to DuVal's representation in Shasta's 483 inspection as incurred to the date of the signing of this Term Sheet, and any amounts owing to Attorney Duval from demands made of Attorney DuVal in 2011, 2012 and 2013 by Ropers where Attorney DuVal provided services based on these demands.
13. PharmaTech will attempt to persuade IPISC to contribute additional funds into the settlement, but such funds are not guaranteed.
14. Shasta will receive 10% of the net monies the Court orders Johnson & Johnson (hereafter "J&J") to pay the defendants relative to damages incurred as a result of the two preliminary injunctions.
15. Shasta will receive 20% of the net monies for attorney's fees granted at the end of the litigation with J&J/LifeScan, if any, and 5% of any litigation damages ordered by the court related to PharmaTech's counter-suits against J&J LifeScan for false advertising and anti-trust.

Broadtree will agree to the following settlement terms:

16. Broadtree will accept \$388,923 as full compensation due under the Shasta Operating Agreement, or any other contract or Agreement (monies, royalties and the like). These monies to be paid directly to Broadtree out of escrow and netted against the \$2,000,000. Broadtree shall pay its prorated share of escrow costs.
17. Broadtree has the option agree to sell, and, if Broadtree exercises this option, Shasta will agree to buy Broadtree's 7.5% membership for one-Dollar (\$1.00) concurrently with the distribution of funds outlined on Paragraph 17 above. Subject to tax implications; see #20 below.
18. Broadtree will receive 7.5%, and Calvin Knickerbocker, Sr., Calvin Knickerbocker, Jr. and Dr. Yu will each receive 30.83% of any monies PharmaTech pays to Shasta as a result of a payment by J&J, if any, resulting from a settlement of the injunction damages, from any other source. Broadtree will receive any such payments directly and not through Shasta.

19. Shasta shall immediately provide a copy of its manufacturing agreement with CTI, and any and all addenda and extensions to that agreement, so that PharmaTech can respond to its 483 Observation letter.
20. This Term Sheet is subject to review and approval by Shasta's tax counsel within the 5-day period prior to \$50,000 payment.

**General Terms:**

21. The term "Shasta" shall mean the existing LLC.
22. The term "PharmaTech" shall mean that division, or any other division of Decision Diagnostics.
23. The term "GenStrip" shall mean any alternative test strip sold by PharmaTech for use in Ultra meters of LS, regardless of strip modifications, brand name, source of manufacturing or where in the world it is sold.
24. Shasta shall receive full releases signed by CTI within the initial the 5 day period and held in escrow until release of all escrowed funds.
25. The terms of this Term Sheet are intended to be binding on all parties pending execution of the Settlement Agreement.
26. Broadtree, its shareholders, employees and or associates, warrant, represent and agree that they, singly or collectively, or through others on their behalf, have not received, nor will receive, any other consideration or compensation for any acts or promises heretofore performed or to be performed regarding PharmaTech's buyout of the GenStrip technology as described herein, other than as is set forth herein, or disclosed by them, in writing, prior to the execution of this agreement.

So Agreed:

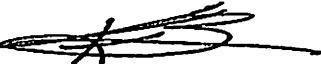
For Shasta Technologies, LLC.

By: \_\_\_\_\_ Date \_\_\_\_\_  
Calvin Knickerbocker, Sr., Managing Member

For Broadtree, Inc.

By: \_\_\_\_\_ Date \_\_\_\_\_  
Rita Chasco, President

For PharmaTech Solutions, Inc.

  
By: \_\_\_\_\_ Date \_\_\_\_\_ March 20, 2014  
Keith Berman, President

19. Shasta shall immediately provide a copy of its manufacturing agreement with CTI, and any and all addenda and extensions to that agreement, so that PharmaTech can respond to its 483 Observation letter.

20. This Term Sheet is subject to review and approval by Shasta's tax counsel within the 5-day period prior to \$50,000 payment.

General Terms:

21. The term "Shasta" shall mean the existing LLC.

22. The term "PharmaTech" shall mean that division, or any other division of Decision Diagnostics.

23. The term "GenStrip" shall mean any alternative test strip sold by PharmaTech for use in Ultra meters of LS, regardless of strip modifications, brand name, source of manufacturing or where in the world it is sold.

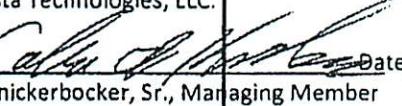
24. Shasta shall receive full releases signed by CTI within the initial the 5 day period and held in escrow until release of all escrowed funds.

25. The terms of this Term Sheet are intended to be binding on all parties pending execution of the Settlement Agreement.

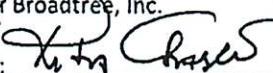
26. Broadtree, its shareholders, employees and or associates, warrant, represent and agree that they, singly or collectively, or through others on their behalf, have not received, nor will receive, any other consideration or compensation for any acts or promises heretofore performed or to be performed regarding PharmaTech's buyout of the GenStrip technology as described herein, other than as is set forth herein, or disclosed by them, in writing, prior to the execution of this agreement.

So Agreed:

For Shasta Technologies, LLC.

By:  Date 3/20/2014  
Calvin Knickerbocker, Sr., Managing Member

For Broadtree, Inc.

By:  Date 03/20/2014  
Rita Chasco, President

For PharmaTech Solutions, Inc.

By: \_\_\_\_\_ Date \_\_\_\_\_  
Keith Berman, President

**EXHIBIT D**

Order Total	Invoice Date Paid	CTI Invoice	Lot	Cases of 24	Boxes	Shasta Unit	Shasta	
4	23-Oct-13	41105	105T	231	5,544	\$1.57	\$ 2,115.00	24-
	Oct-13	x						
5	25-Oct-13	41112	106T	164	3,936	\$1.57	\$6,179.52	25-Oct-13
		x						
6	25-Oct-13	41113	107T	237	5,688	\$1.57	\$8,930.16	25-Oct-13
		x						
7	28-Oct-13	41116	108T	259	6,216	\$1.57	\$9,759.12	28-Oct-13
		x						
8	30-Oct-13	41124	109T	222	5,328	\$1.57	\$8,364.96	30-Oct-13
		x						
9	31-Oct-13	41128	110T	213	5,112	\$1.57	\$8,025.84	4-Nov-13
		x						
10	4-Nov-13	41129	112T	212	5,088	\$1.57	\$7,988.16	6-Nov-13
		x						
11	6-Nov-13	41146	114A	258	6,192	\$1.57	\$9,721.44	8-Nov-13
		x						
12	6-Nov-13	41153	115A	238	5,712	\$1.57	\$8,967.84	12-Nov-13
		x						
13	13-Nov-13	41167	116A	241	5,784	\$1.57	\$9,080.88	18-Nov-13
		x						
14	13-Nov-13	41168	117A	242	5,808	\$1.57	\$9,118.56	18-Nov-13
		x						
15	15-Nov-13	41176	120A	221	5,304	\$1.57	\$8,327.28	25-Nov-13
		x						
16	27-Nov-13	41212	125A	113	2,712	\$1.57	\$4,257.84	3-Dec-13
		x						
17	2-Dec-13	41217	126A	243	5,832	\$1.57	\$9,156.24	3-Dec-13
		x						
Total				3,094	74,256		\$109,992.84	

*-2X.10 -*

**EXHIBIT E**



Bank of America 

PAGE 1 OF 1

BANK OF AMERICA, N.A.

WIRE TRANSFER ADVICE

1 FLEET WAY

PA6-580-04-05

SCRANTON, PA

18507

00000000000000000000000000000000  
 NX 0000 026 011000 11001 AF 0.384  
 PHARMA TECH SOLUTIONS, INC  
 DIRECT CREDIT ACCOUNT  
 2660 TOWNSGATE RD STE 300  
 WESTLAKE VILLAGE, CA 91361-5717

DATE: 09/23/13  
 DIRECT INQUIRIES TO:  
 800.729.9473 OPTION 2  
 ACCOUNT: 000668960470

THE FOLLOWING WIRE WAS CREDITED TODAY:

TRANSACTION REF: 2013092300268604  
 SENDER'S REF: 2013092300107411  
 IMAD: 2013092311B7031R031365  
 ORIGINATOR: EXCELL ADVISORS LLC  
 SENDING BANK: WELLS FARGO BANK, NA  
 BENEFICIARY: PHARMA TECH

USD AMOUNT \$15,000.00

SERVICE REF: 031365  
 RELATED REF: 000000291  
 ID: 002000018130805  
 ID: 121000248  
 ID: 0668960470

THE FOLLOWING WIRE WAS DEBITED TODAY:

TRANSACTION REF: 2013092300281971  
 BENEFICIARY: CONDUCTIVE TECHNOLOGIES INC  
 BENEFICIARY'S BANK: PNC BANK, NATIONAL ASSOCIATION  
 PAYMENT DETAIL: FIRST PAYMENT TOWARD INV# 40967

USD AMOUNT \$24,000.00  
 SERVICE REF: 009173  
 IMAD: 20130923B6D7HU3R009173  
 ID: 5004321015  
 ID: 031000053



PAGE 1 OF 1  
BANK OF AMERICA, N.A.  
WIRE TRANSFER ADVICE  
1 FLEET WAY PA6-580-04-05  
SCRANTON, PA 18507

DATE: 10/07/13  
DIRECT INQUIRIES TO:  
800.729.9473 OPTION 2  
ACCOUNT: 000668960470

THE FOLLOWING WIRE WAS CREDITED TODAY:

USD AMOUNT \$5,500.00

TRANSACTION REF:	2013100700252622	SERVICE REF: 004641
SENDER'S REF:	F1S1310073776400	
IMAD:	20131007D1Q8151C004641	
ORIGINATOR:	JERROLD FRANKEL 27 BERMAN COURT PHO	ID: 40J0193861
ORIGINATOR'S BANK:	PERSHING LLC	ID: PRSHUS33
SENDING BANK:	THE BANK OF NEW YORK MELLON	ID: 021000018
BENEFICIARY:	PHARMA TECH SOLUTIONS INC	ID: 06689-60470
YMENT DETAIL:	/BNF/RE: JERROLD FRANKEL THIS IS FO//R AN INVESTMENT //40J019386 ////F W021000358 //BANK OF AMERICA //WESTLAKE VILLAGE CA	

THE FOLLOWING WIRE HAS DEBITED TODAY:

USD AMOUNT \$24,000.00

TRANSACTION REF: 2013100700176115 SERVICE REF: 004569  
BENEFICIARY: CONDUCTIVE TECHNOLOGIES INC. IMAD: 20131007B6B7HU1R004569  
BENEFICIARY'S BANK: PNC BANK, NATIONAL ASSOCIATION ID: 5004521015  
PAYMENT DETAIL: FEE FINAL PAYMENT TOWARD REPACKAGING. ATTN: KARIN ID: 031000053

PAYMENT DETAIL: REF FINAL PAYMENT TOWARD REPACKAGING, ATTN KARIN

**EXHIBIT F**

CONDUCTIVE TECHNOLOGIES INC.  
Aged Receivables

8/6/2014  
Page

8:48 AM  
1

Customer 80393 All Currencies, As of 8/6/2014, Aged By Invoice Date, 2.1.1.2.1.0.000

InvoiceID	Date	INV AMOUNT	Current 30	Over 30	Over 60	Over 90	Over 120	Total
80393 DECISION DIAGNOSTICS CORP., (A) 042 MUSHO, KARIN FINK								
41803	5/28/2014	257,500.00	0.00	0.00	257,500.00	0.00	0.00	257,500.00
41934	6/25/2014	30,405.60	0.00	30,405.60	0.00	0.00	0.00	30,405.60
41933	6/25/2014	30,776.40	0.00	30,776.40	0.00	0.00	0.00	30,776.40
Customer Totals			0.00	61,182.00	257,500.00	0.00	0.00	318,682.00
Report Totals:			0.00	61,182.00	257,500.00	0.00	0.00	318,682.00
			.000%	19.2.0%	80.80%	0.00%	.000%	100.00%

- EX. F -

**EXHIBIT G**

CTI  
BOX/INSERT INVENTORY AT T/G AS OF 7/18/14

Obsolete GenStrip Packaging Material On Hand

Item#	Description	Each	Pallets	Unit Cost	Extended Cost	
0850BOX	SHASTA GENSTRIP TEST STRIP CARTON	0	0	Green Box 2010	\$0.00	
0850BOX-2	SHASTA GENSTRIP TEST STRIP CARTON REV 07/2013	307,000	7	Green Box 2013	\$0.0850	\$26,095.00
0850BOX-3	SHASTA GENSTRIP TEST STRIP CARTON REV 09/2013	96,360	4	Purple Box 2010 old	\$0.1362	Paid
0850INSERT	SHASTA GENSTRIP PRODUCT INFORMATION INSERT	18,880	2	Original 2010	\$0.1210	\$2,284.48
0850INSERT-2	SHASTA GENSTRIP PRODUCT INFORMATION INSERT REV 07/2013	208,000	3	2013	\$0.0590	\$12,272.00
0850INSERT-3	SHASTA GENSTRIP PRODUCT INFORMATION INSERT REV 10/2013	341,460	7	2013	\$0.0590	\$20,146.14
0850INSERT-4	SHASTA GENSTRIP PRODUCT INFORMATION INSERT REV 02/2014	81,860	2	2010 old	\$0.0854	Paid
Original Label		146,750		Green 2010	\$0.0522	\$7,660.35
Green Label	Green 2013	72,000		Green 2013	\$0.0218	\$1,569.60
Green Label	Dated 2013	312,000		Green 2013	\$0.0218	\$6,801.60
Purple Label	Dated 2010 old	52,000		Purple 2010 old	\$0.0414	

\$76,829.17

-EX. G -